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FÃ©minas: A Longitudinal Cohort Study Integrating Gender-Affirming Primary Care and Peer Navigation with HIV Treatment and Prevention Services to Improve the Health of Transgender Women

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FÃ©minas: A Longitudinal Cohort Study Integrating Gender-Affirming Primary Care and Peer Navigation with HIV Treatment and Prevention Services to Improve the Health of Transgender Women

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Abstract

Background: Public health strategies are urgently needed to improve HIV disparities among transgender women, including holistic intervention approaches that address those health needs prioritized by the community. Hormone therapy is the primary way many transgender women medically achieve gender identity affirmation. Peer navigation has shown to be effective to engage and retain underserved populations living with HIV in stable, primary medical care.

Objective: To assess the acceptability and effectiveness of an integrated innovative HIV service delivery model designed to improve HIV care cascade, by combining gender-affirming primary care and peer navigation with HIV treatment and prevention services. Specifically, we aim to assess at the end of the intervention, the 1) proportion of HIV negative participants who undergo regular HIV testing and linkage to preventive services; and the 2) proportion of HIV positive participants who link to and are retained in care, adhere to antiretroviral treatment and result in viral suppression.

Methods: A 12-month, non-randomized, single-arm, cohort study was implemented in Lima, Peru among adult individuals, assigned a male sex at birth, who identified themselves as male-to-female transgender, regardless of initiation or completion of gender enhancement procedures, and who were unaware of their HIV serostatus or were living with HIV but not linked in routine HIV care. HIV positive participants were indicated to initiate standard antiretroviral treatment and underwent quarterly plasma HIV-1 RNA and peripheral CD4+ lymphocyte cell count monitoring. HIV negative participants received quarterly HIV testing and risk reduction counseling. All participants received feminizing hormone therapy supply on a monthly basis and adherence counseling and education on their use. Peer health navigation facilitated retention in care by outreach work, social media, and phone contact.

Results: Patient recruitment started in October 2016 and final inclusion was March 2017. The cohort ended follow-up on March 2018. Data analysis is currently underway.

Conclusions: Innovative and culturally sensitive strategies to improve the HIV care cascade among transgender women are vital to curb the burden of HIV morbidity and mortality for this key population and prevent HIV transmission to their sexual partners. Findings of this intervention will inform future policies and research, including evaluation of its efficacy in a randomized controlled trial.

ClinicalTrial: The study is registered at Peru National Institute of Health (Registro Nacional de Investigaciones en Salud

EI00000345) and Clinicaltrials.gov (Registration Number: NCT03757117).

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Title: *Féminas*: A Longitudinal Cohort Study Integrating Gender-Affirming Primary Care and Peer Navigation with HIV Treatment and Prevention Services to Improve the Health of Transgender Women

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ABSTRACT

Background: Public health strategies are urgently needed to improve HIV disparities among transgender women, including holistic intervention approaches that address those health needs prioritized by the community. Hormone therapy is the primary way many transgender women medically achieve gender identity affirmation. Peer navigation has shown to be effective to engage and retain underserved populations living with HIV in stable, primary medical care.

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Trial registration: The study is registered at Peru National Institute of Health (Registro Nacional de Investigaciones en Salud EI00000345) and Clinicaltrials.gov (Registration Number: NCT03757117).

Keywords: Transgender women; gender affirming care; patient navigation; HIV cascade; health services; Peru

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BACKGROUND

Globally, transgender women (TW) are at high risk for HIV infection with a pooled 19.1% prevalence, a 48.8-fold increased odds of HIV compared to the general adult population (1). Public health strategies are urgently needed to improve global HIV disparities among TW, including intervention approaches that address those health needs prioritized by the community (2). In Peru, TW are disproportionately burdened by the HIV epidemic, with HIV prevalence estimates ranging from 30% to close to 45% (3-5) compared with less than 1% in the general population (6). About 22,500 TW live in Lima (7), the national capital and regional center, which is home of 80% of Peru´s HIV epidemic (8), making it a key site for HIV interventions in Latin America. Improving the HIV continuum of care among TW in Peru is vital to curb the burden of HIV morbidity and mortality for this key population and prevent HIV transmission to their sexual partners (9).

Gender affirmation is defined as the process of being recognized in one's internal felt gender and sense of oneself as having a particular gender identity (10, 11). Hormone therapy is the primary way many TW medically achieve gender identity affirmation (12), as some consider body modification an important step in aligning their outward physical gender presentation with their internal felt sense of their gender (11). The implementation of gender-affirming care has been shown to improve psychological well-being among TW (13, 14). Further, studies suggest that integration of culturally competent gender-affirmative care, including delivery of cross-sex hormone therapy, may facilitate TW engagement in the entire HIV continuum of care (15, 16). Integrating hormone therapy with HIV prevention and care may increase patient-provider trust, correct TW misconceptions regarding drug-drug interactions between antiretroviral medications and hormones shown to impede HIV prevention and treatment uptake and adherence among TW, foster positive interactions, reduce barriers to obtaining needed services, and support ongoing engagement and retention in HIV care (16, 17).

Further evidence from Peru highlights insufficient culturally competent clinical services to

implement cross-sex hormone therapy for TW (18). As a result, gender affirmation procedures usually occur outside the health system in informal peer-delivered systems (4). In this setting, trained TW community members as educators and/or peer navigators, could improve gender-affirming medical care and also, be involved into and support HIV service delivery programs, as research demonstrated the effectiveness of peer navigation to engage and retain underserved populations living with HIV in stable, primary medical care (19).

To address HIV disparities among TW, the *Féminas* (the plural form of *Fémina* in Spanish, meaning *Feminine* in English) study was designed to improve the HIV care cascade among TW in Lima, Peru via an innovative service delivery model that integrates HIV prevention and treatment services with gender-affirming transgender medical care supported by peer navigation. The study was grounded in an implementation science framework, which aimed to test and translate research to promote evidence-based practices for improving health and well-being (20, 21). Specific design considerations were given to elements that could be replicated by different institutions, including the Ministry of Health, non-governmental organizations and community based organizations (CBOs) providing HIV care for TW, and/or researchers seeking to develop health interventions culturally tailored to the needs of TW.

METHODS

Study Design. Between October 1, 2016 and March 31, 2017, a twelve-month, non-randomized, single-arm, cohort study was enrolled in Lima, Peru to assess the acceptability and effectiveness of integrating routine HIV prevention and treatment services with gender-affirming care (i.e., feminizing hormone therapy) supported by TW community peer health navigators.

The study was led by Asociacion Civil Impacta Salud y Educacion (IMPACTA), a non-governmental HIV research organization, in partnership with Epicentro, a CBO that provides low-cost HIV and sexually transmitted infection (STI) testing and care, community services, and hosts

volunteer-driven community activities, which served as research site for all study operations. The Fenway Institute at Fenway Health, a leading center of transgender clinical care, training, education, and research in Boston, Massachusetts, USA served as a research partner. Fenway Health's informed consent of transgender care and community-based transgender health research (22) were the basis for the *Féminas* intervention in Lima Peru.

Adult individuals, ages ≥18 years, assigned a male sex at birth, who identified themselves as male-to-female transgender or on the trans-feminine continuum (e.g., "trans", "travesti", "transgender", "transsexual"), regardless of initiation or completion of gender enhancement procedures, and who were unaware of their HIV serostatus or were living with HIV but not linked in routine HIV care, were eligible to participate.

Community Engagement and Education. To enhance community engagement and following principles of Good Participatory Practice to ensure ethical and scientific integrity (23, 24), a Task Force composed of TW community representatives was convened for the study. The Task Force, acting as a community advisory board, informed the investigators on community issues, advised on study design, supported development of educational programs and campaigns, and facilitated collaborations with the study population. The Task Force also played a pivotal role in creating the *Féminas* house, as a separate stand-alone community facility and space for healthcare, support, and community programming placed at Epicentro. Community mobilization activities conducted at this setting were coordinated by a member of the TW community. Tailored annual community engagement and education plans were designed in advance of study implementation to include: (a) formative research for stakeholder identification and educational material validation; (b) community awareness activities; and (c) study communication, including development of educational materials, community consultations, and communication of study results.

Mixed-Methods Formative Research. Formative research was conducted among TW to assess: (a) experiences accessing HIV care services; (b) needs related to HIV care and gender-

affirmation; (c) experiences with previous and current use of feminizing hormone therapy; (d) attitudes toward a peer navigation system to increase engagement in care; and (e) attitudes toward having a dedicated facility to receive gender-affirmative care. Formative research included healthcare professionals to assess: (a) knowledge of and experience providing feminization hormone therapy; (b) feasibility and acceptability of providing cross-hormone therapy with the existing public health system; (c) acceptability and willingness to provide cross-sex hormone therapy; and (d) perceptions of stigma and discrimination resulting from providing hormone therapy to TW. Both TW and healthcare professionals were also queried about: perceived acceptability of intervention components; and potential barriers to intervention success (18, 25).

This formative research found high perceived acceptability of the proposed integrated care model among both TW and healthcare professionals and informed the *Féminas* intervention, including all study procedures and protocols. Identified barriers for the implementation of the intervention included lack of provider training and absence of Peruvian guidelines regarding optimal TW medical care and service delivery obstacles (e.g., legal documents, spatial placement of clinics, hours of operation). Hiring TW peer health navigators was also identified as a key facilitator for engagement in health care (18, 25).

Training. Formative research informed the development of training plans to educate study providers, peer health navigators, and community stakeholders on the hormone therapy intervention. TW community representatives and healthcare providers received medical education training in health care needs, services, and strategies including a gender affirmative approach to transgender medical care, cross-sex hormone therapy, managing HIV infection, and the peer health navigation to improve linkage and retention in care.

Recruitment. Purposive sampling was used to recruit potential participants. Peer recruiters conducted outreach work by visiting TW-specific socialization venues, where they approached

potential participants and referred them to the research site for screening. This recruitment strategy was complemented by social media initiatives to promote study participation.

Screening. Counselors explained the study objectives to volunteers and obtained written informed consent to be screened for participation, HIV and sexually transmitted infection (STI) testing, sample storage for future testing in ancillary studies, and contact for future studies. Participants who agreed and provided voluntary informed consent underwent a computer-assisted self-interview (CASI) to assess demographics, gender identity, sexual orientation and role, sexual risk behavior, previous HIV testing and diagnosis, history of body enhancement procedures and hormone therapy use, life expectations, problems and barriers perceived due to being TW, HIV testing history, and prior engagement in care, if HIV positive. Counselors assisted participants in cases of computer unfamiliarity. Physicians obtained a brief medical history and performed a targeted physical examination. A peripheral blood sample was obtained for assessment of HIV, syphilis, hepatitis B virus (HBV) and hepatitis C virus (HCV) infection, as well as hematology and biochemistry laboratory tests. Participants underwent oropharyngeal and rectal swabbing, and provided a urine sample for the diagnosis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection. An anal cytobrush was used to assess the presence of cytological abnormalities induced by human papillomavirus infection. Participants were asked to provide two sputum samples and undergo a chest x-ray to rule out active tuberculosis. Volunteers were convened to return to the research site in 2 weeks for the provision of results and enrollment if they were eligible and agreed to participate (Table 1).

Enrollment. Peer health navigators remained in contact with screened participants and facilitated their return to the research site for enrollment. At the site, a physician assessed eligibility, which included TW who resided in Lima and normal hematology and biochemistry laboratory results. Individuals presenting with active tuberculosis, history of pancreatitis, severe or depending alcohol or drug consumption, severe medical comorbidity, reporting the use of immunosuppressive,

nephrotoxic or hepatotoxic therapy, or having any other health condition that in the opinion of the investigator would interfere with the evaluation of the study objectives were excluded. Volunteers received a detailed explanation of the risks and benefits of the medical intervention. Consenting participants underwent a CASI questionnaire, which included questions about personal and social network support for resilience to societal stigma and discrimination, hormone therapy expectations, and housing. A peripheral blood sample was obtained for assessment of baseline fasting glucose and lipids, estradiol and total testosterone levels. All participants were prescribed and dispensed with feminizing hormone therapy, and invited to initiate HIV care as described below (Table 1).

Follow-up. Participants were asked to return to research site for study visits at months 1, 3, 6, 9 and 12, which included clinical and laboratory safety assessment, and hormone therapy adherence counseling and education following standard protocols (26). At quarterly visits, participants underwent HIV (for those negatives) and syphilis testing, and answered a CASI questionnaire on gender identity and body image sexual risk behavior, substance use, attitudes toward HIV testing, personal and social network support, hormone therapy expectations, mental health, adherence to hormone therapy, and involvement in TW community building activities (Table 1). The occurrence of laboratory Grade ≥2 and clinical Grade ≥3 adverse events was monitored in all follow-up visits. All participants were instructed to report the occurrence of unintended effects of the trial at any time. Peer health navigation facilitated retention in care and promoted adherence to study procedures, HIV care and hormone therapy by outreach work, social media, and phone contact.

Regimen for Feminizing Hormone Therapy. Hormone therapy was prescribed at discretion by study physicians and dispensed on site on a monthly basis. Dosage varied according to individual responses but followed standard protocols for drug dose change in response to clinical efficacy or the occurrence of harms (26). Estradiol valerate was initiated at 2 mg PO daily and increased to 4 mg after 4 to 12 weeks. Antiandrogen therapy with spironolactone started at a dose of 50 mg daily and indicated to be increased every 4 weeks to 200 mg daily (26).

HIV and STI Care. All participants received risk reduction counseling, condoms and lubricants when tested for HIV and/or STI. Participants diagnosed with HIV infection were invited to be linkage to HIV care at IMPACTA, placed four blocks away from the research site Epicentro, where local standard care was offered, including initiation of antiretroviral therapy (ART) and assessment of baseline and quarterly plasma HIV-1 RNA and CD4+ lymphocyte cell count monitoring (27). HIV negative participants were invited to initiate standard HIV pre-exposure prophylaxis with daily oral emtricitabine/tenofovir disproxyl fumarate (28), which was available at the site at no cost. Participants diagnosed with non-HIV STI received international standard treatment and those susceptible to HBV were referred for vaccination (29).

Peer Health Navigation. Socially well-connected community members representing the diverse subcultures of TW in the city were convened and trained to provide services, skills and confidence to help TW self-manage their healthcare needs with the ultimate goal to facilitate engagement in study procedures and retention in follow-up (19).

Laboratory Procedures. HIV antibody screening was conducted on whole blood using Determine HIV-1/2® (Alere, Waltham, MA), a point-of-care third-generation HIV antibody test. Positive samples were sent for confirmatory testing to the Peru National Institute of Health (NIH) by means of indirect immunofluorescence, unless a previous positive confirmatory result was identified in the Peru NIH database. Plasma HIV-1 RNA and CD4+ T cell count assessments were also conducted at the Peru NIH. Antibodies to *Treponema pallidum* were detected using a rapid plasma reagin test (RPR Quicktest®, Stanbio, Boerne, TX) and confirmed by a *T. pallidum* particle agglutination assay (DR0530, TPPA Test®, Oxoid Limited, Basingstoke, UK). Both HBV (HBsAg, anti-HBc and anti-HBs) and anti-HCV serologies were tested by means of chemoluminescent microparticle immunoassay (Architect®, Abbott, Abbott Park, IL). *N. gonorrhoeae* and *C. trachomatis* infections were diagnosed by GeneXpert® CT/NG (Cepheid, Sunnyvale, CA). Cytological slides were manually colored using standard Papanicolau staining. Sputum testing for

tuberculosis used the Ziehl-Neelsen stain. Hematology (XS-1000i® Sysmex America, Inc, Lincolnshire, IL) biochemistry (IFCC Vitros®, Ortho Clinical Diagnostics, Raritan, NJ) and hormone (Cobas® E-601, Roche Diagnostics, Indianapolis, IN) tests were assessed automatically. All laboratory test results were provided to participants within a maximum of 14 days.

Endpoints. At baseline: (a) proportion of participants who had ever been tested for HIV; and (b) proportion of participants newly diagnosed as HIV infected. At the end of the intervention (12-month follow-up): (a) proportion of HIV negative participants at baseline who underwent regular HIV testing and linkage to preventive services; (b) proportion of HIV positive participants at baseline who linked to and were retained in care, adhered to ART and resulted in viral suppression (30). Occurrence of study endpoints were assessed by an endpoint adjudication committee composed by the primary study principal investigator and study coordinator.

Data Management and Monitoring. All participants' data were anonymized but not de-identified. All participants were identified with a unique alphanumeric code. The link between the participants' codes and identification was restricted to the study coordinator and his back-up. It was stored in an electronic file and double password protected. Data was monitored for completeness, consistency and accuracy, as well as for the occurrence of adverse events, in a monthly basis by a study data monitoring committee composed by the study principal investigators and coordinators.

Statistical Considerations. The target enrollment was 220 TW for a total of 200 completers (>90% retention during 12-months of follow-up) (Table 2). Based on these estimated percentages and assuming a moderate correlation across measurements (rho=0.30) (31), the power to detect statistically significant differences across follow-up for all HIV cascade outcomes is >0.80. Quantitative analyses will be implemented in Stata SE 13.0 (Stata Corp, College Station, TX) software using two-tailed tests of significance, with statistical significance at the alpha 0.05-level. A generalized estimating equation (GEE) approach will be used (31-33) with robust standard errors which is an extension of regression analysis that properly accounts for repeated measures.

Descriptive statistics will be obtained to summarize all variables. Bivariate tests (t-tests/X^2 adjusted longitudinally using GEE) will examine changes in the proportion of TW across outcomes of interest, followed by multivariable longitudinal models adjusted for covariates (e.g., age, etc.). GEE models utilize the number of observations as data points over time (5 visits x 200 TW = 1000 observations). Multiple imputation (34, 35) will be used if missingness is differential.

Secondary analyses characterizing patterns of HIV virologic suppression over time will also be implemented. HIV cascade outcomes are also time to event data beyond the achievement of the dichotomous outcomes we propose. Therefore, data will be collected that allow us to capture the time at which an event of particular interest occurred (i.e., virological suppression). Patterns of change in biomarkers (i.e., CD4+ cell count decrease) or the association between the primary endpoint and features of the longitudinal profiles are of interest. We will conduct joint modeling that enables longitudinal repeated biomarker measurements and survival processes to be modeled simultaneously while taking account the association between them (36-38). The random effects model for longitudinal data will be included in the survival model. Joint modeling provides less biased estimates and more efficient inferences than a two-stage modeling approach (39-41). We will use SAS software R package (42). The joint modeling approach is well-suited for our study because there is no control group (which is best suited for implementation science) and within-person change across time is being assessed.

Protection of Human Subjects. All participants were reimbursed approximately $13 USD in local currency (40 Soles) at each study visit. The study protocol and its amendments, informed consent forms, and recruitment and educational materials were approved by the IMPACTA´s Institutional Bioethics Committee in compliance with all applicable Peruvian and U.S. Federal regulations governing the protection of human subjects. All participants provided written informed consent for study screening and participation, receiving cross-sex hormone therapy, HIV and sexually transmitted infection testing, sample storage for future testing, and contact for future

studies. The study protocol, version 1.1 dated on October 1, 2016, is registered at Peru National Institute of Health (Registro Nacional de Investigaciones en Salud EI00000345; dated on May 29, 2018) and Clinicaltrials.gov (Registration Number: NCT03757117; dated on November 28, 2018).

Post-Trial Care Access. At the end of the intervention, all participants will be invited to continue receiving HIV and STI prevention and treatment care at IMPACTA or referred to healthcare centers of the Peru Ministry of Health to receive it. It is expected that by time study ends, feminizing hormone therapy will become available at public healthcare centers as part of the Ministry of Health policies to provide integral care to TW (43).

Dissemination. When intervention is near completion, the study team will prepare communication plans for disseminating and interpreting study results. We will host a preparatory activity of study results as a forum on the implications of the intervention targeting Ministry of Health representatives and the scientific and community stakeholders. This will include a cost-effectiveness analysis. In this forum, we will present a draft version "Best Practices" for dissemination of integrated TW health care services and ask audience for input that will be further incorporated. Then, we will prepare the TW community for the disclosure of the results in a participant appreciation event.

RESULTS

Patient recruitment started in October 2016 and final inclusion was March 2017. The cohort ended follow-up on March 2018. Data analysis is currently underway, and the first results are expected to be submitted for publication in June 2019.

DISCUSSION

The *Féminas* study will investigate the acceptability and effectiveness of an innovative service delivery model that integrates HIV prevention and treatment services with gender-affirming

transgender medical care supported by peer navigation, to improve the HIV care cascade among TW in Lima, Peru. To our knowledge, interventional research has not yet combined these three aspects for TW primary medical care.

For the successful of the intervention, transgender community engagement is essential. We promoted community mobilization through the implementation of community engagement and education plans, which were structured by members of the own community in response to their health needs. Study procedures were implemented at a culturally competent CBO accustomed to regularly providing services for TW residents in Lima. The TW Task Force was particularly crucial in the beginning of the project to gather input on the study design and implementation and offer a vision of the model that would be maximally responsive to the needs of the population. The coordinator of the *Féminas* house had a challenging role given her proximity to the community and the many demands placed upon her in terms of the project and by her peers. The coordinator position must have supportive and ongoing supervision that is gender affirming with a person (or people) who are knowledgeable about TW communities and not necessarily within trans communities. This supervision needs to include ongoing assistance trouble-shooting any number of challenging situations that can arise between the personal and professional aspects of project coordination and strategizing how best to manage “insider” trans women community politics with other peer leaders and organizations.

The competent provision of feminizing hormones with all services along the HIV prevention and treatment cascade appear attractive for TW and seems it is important aspect for future implementation of this model.

Peer navigation is vital for the *Feminas* model of care. At every initial point of contact and visit, participants have social, medical, legal, and other needs, which necessitate referrals and assistance. The peer health navigation takes a great deal of staff time and effort, much more than originally anticipated and budgeted given the many challenges and barriers to services facing trans

women in Lima in the broader context of social and economic exclusion and marginalization. Appropriate and realistic staffing and effort for peer health navigation is an important future consideration for the model. In addition, there are many types of and approaches to peer navigation however surprisingly few curricula exist to operationalize and skill-build peer health navigators. Compiling and creating manualized curricula to train on peer health navigation is an important next step.

The anticipated challenges inherent in studying at-risk populations include high participant attrition and low enrollment, as well as, high rates of lost to follow-up. We have built a system robust against attrition through comprehensive collection of information on how to locale and contact participants, active tracking and engagement of participants between appointments using peer navigation and reimbursement to minimize loss to follow-up.

Findings will inform future policies and research, including evaluation of the efficacy of the *Féminas* intervention in a randomized controlled trial.

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Abbreviations: ART: Antiretroviral therapy; CASI: Computer-assisted self-interview; CBO: Community based organization; GEE: Generalized estimating equation; HBV: Hepatitis B virus; HCV: Hepatitis C virus; IMPACTA: Asociacion Civil Impacta Salud y Educacion; NIH: National Institute of Health; STI: Sexually transmitted infection; TW: Transgender women.

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DECLARATIONS

Ethics approval and consent to participate: This study was approved by the Institutional Bioethics Committee of Asociacion Civil Impacta Salud y Educacion (Certificado de Aprobación N° 0113-2016-CE dated on May 16, 2016) in compliance with all applicable Peruvian and U.S. Federal regulations governing the protection of human subjects. All participants provided written informed consent for study screening and participation, receiving cross-sex hormone therapy, HIV and sexually transmitted infection testing, sample storage for future testing, and contact for future studies.

Consent for publication: Not applicable.

Availability of data and materials: The dataset (anonymized) generated during this study would be made available for interested parties on request once the study outcomes of the study were assessed. The study protocol and informed consents are available upon request.

Competing interests: The authors declare they have no competing interests.

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Authors´ contribution: JRL, KHM, JS and SLR conceptualized and designed the study; JRL, KHM, AGP-B, LH, HS, JLC, JS and SLR wrote the study protocol; JRL, KHM, AGP-B, JLC and SLR drafted the manuscript. All authors read and approved the final version of the manuscript for

publication.

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Table 1. Study schedule of events

Procedures	Screening	Post-Entry Evaluations (Months)[a]												
		0	1	2	3	4	5	6	7	8	9	10	11	12
Informed consent	X	X												
Risk reduction counseling	X				X			X			X			X
Medical history	X													
Medication history	X													
Clinical assessment	X		X		X			X			X			X
Complete physical exam	X													
Targeted physical exam			X		X			X			X			X
Computer-assisted self-interview	X				X			X			X			X
Complete blood count	X		X		X			X						X
Liver and renal function tests	X		X		X			X						X
Fasting glucose and lipids		X						X						X
Estradiol and total testosterone		X			X			X						X
Sputum samples for tuberculosis screening	X													
Chest X ray	X													
HIV and sexually transmitted infection care														
N. gonorrhoeae and *C. trachomatis* (pharynx, rectum and urine)	X													
Anal cytological abnormalities	X													
Syphilis serology	X				X			X			X			X
Hepatitis B, hepatitis C and HSV-2 serology	X													X[b]
HIV serology (all participants – baseline)	X													
HIV serology (all negative participants at baseline)					X			X			X			X
CD4+ cell count (all HIV positive participants)		X						X						X
HIV-1 RNA (all HIV positive participants)		X			X			X						X

Antiretroviral treatment provision		X			X			X			X			X
Feminizing hormone therapy														
Adherence counseling and education		X	X		X			X			X			X
Dispensation		X	X	X	X	X	X	X	X	X	X	X	X	X
Peer health navigation support	X	X	X	X	X	X	X	X	X	X	X	X	X	X

[a] Visits to occurr every 30 days +/- 5 days

[b] Hepatitis B serology for those hepatitis B seronegative at baseline

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Table 2. Projected sample sizes across HIV cascade outcomes

Cascade Stage	Baseline N=200	12-months	Difference in Proportions (p)	Outcomes
	N (%)	N (%)		
HIV test and risk reduction counseling in past 3 months	75 (37.5)	195 (95.0)	57.5	↑p of TW who know their HIV status
HIV-infected	46 (23.0)	66 (33.0)	10.0	Identify new HIV infections in TW
Link HIV-infected TW to care	22 (47.8)	66 (100.0)	52.2	↑p of HIV-infected TW linked to care
Retain HIV-infected TW in care	9 (40.9)	60 (90.9)	50.0	↑p of HIV-infected TW retained in care and treatment
Prescribed ART	11 (50.0)	60 (90.9)	40.9	↑p of HIV-infected TW prescribed ART
Virally Suppressed	5 (45.5)	50 (83.3)	37.8	↑p of HIV-infected TW who are virally suppressed
HIV-uninfected	154 (77.0)	134 (67.0)	10.0	Identify high-risk HIV-uninfected TW
HIV-uninfected TW who complete referrals to HIV prevention services	35 (22.7)	70 (52.2)	29.5	Link high-risk HIV-uninfected TW to HIV prevention services
STI screening, risk reduction counseling, and treatment in past 3 mo	50 (25.0)	200 (100.0)	75.0	Increase the proportion of TW screened and treated for STIs

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Figure 1. Schematic of gender-affirming healthcare and peer navigation to improve the HIV cascade

ART: Antiretroviral therapy

PrEP: Pre-exposure prophylaxis

STI: Sexually transmitted infection

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Figures

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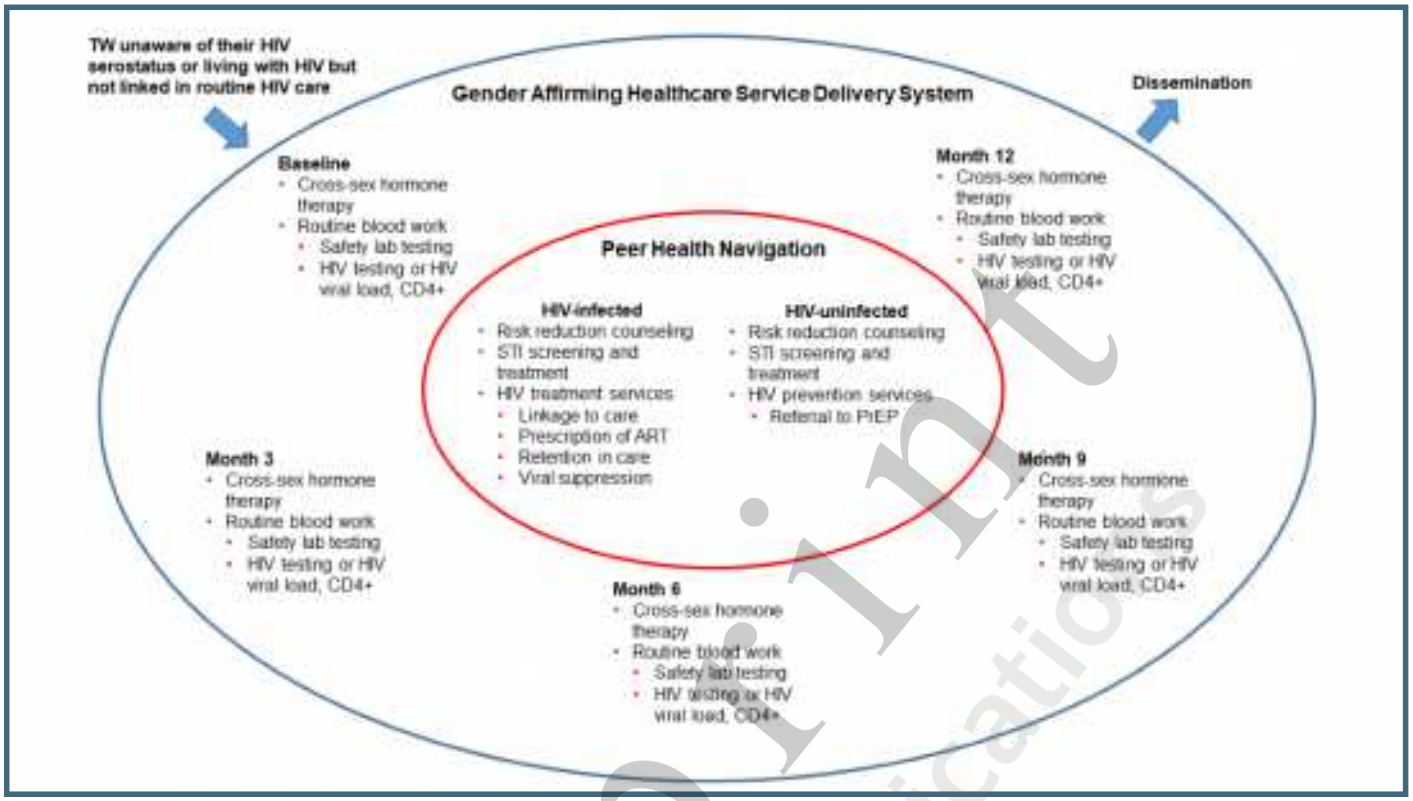
Figure 1. Schematic of gender-affirming healthcare and peer navigation to improve the HIV cascade.



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